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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/449,093 Filing Date: November 24, 1999 Appellant(s): HARTAL ET AL. MAILED
FEB 1 5 2005
GROUP 1700

Sheridan Neimark
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/29/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

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A statement identifying the related appeals and interferences that will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellants' statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention -

The summary of invention contained in the brief is somewhat misleading. Appellants state that "heating is therefore disadvantageous, and the problem with conventionally extracted lycopene is that its exposure to oxygen, particularly under the effects of even only moderate heat cause the lycopene to lose it bright red color." On page 1, fourth paragraph, the section of the specification that appellants refer to provide basis for the above assertion, makes no mention of lycopene specifically, but only refers to "natural colors," clearly a very broad category of chemicals. With regard to oxidation, it appears that only some colors are affected by it and there is no connection between the presence of oxygen and the use of heat.

In fact, the specification states that lycopene, when found in its natural state, i.e., in intact and partially broken chromoplasts, has "been found to be relatively insensitive to the effects of heat and oxidation." (Page 7, first paragraph). Further, appellants state that the instant product can be pasteurized, i.e., heated to high temperatures to kill microorganisms and thereby aid in its

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preservation. Therefore, it is not clear how appellants can state that lycopene suffers from heat and/or oxidation, when this is clearly not the case, as disclose by appellants in their specification.

Appellants also state "the processes of making these conventional tomato products causes destruction of the chromoplast membrane." (Brief, page 5, lines 3-5). There is no citation for this statement, nor was one found. It is not clear what processes appellants refer to, and it appears that appellants utilize the same processes as the prior art. Certainly, there is no description of what specific processes would destroy chromoplast particles.

Appellants state that a "key aspect of the present invention therefore is to liberate the chromoplast from the fruit without causing substantial mechanical breakage . . . of the chromoplast particle." (Id., bottom). While they reference page 6, of their specification, there is no mention of "substantial mechanical breakage." Further, the specification states that the "coloring material of the invention comprises, as the color imparting agent, . . . partially broken chromoplast particles containing crystalline lycopene. (Page 6, bottom). What amounts of chromoplast particles are broken is never disclosed.

What is most baffling about the disclosure of the invention is why, if the chromoplast particles (some being broken) are so inherently insensitive to heat and oxidation, the lycopene crystals are destroyed in the prior art processes (that apparently utilize heat and oxidation), when said lycopene crystals are protected within the chromoplast particles. There is nothing in the disclosure that discusses this aspect of the invention.

(6) Issues

The appellants' statement of the issues in the brief is correct.

(7) Grouping of Claims

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Appellants' brief includes a statement that the claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5245095	Graves et al	9-1993
4181743	Brumlick et al.	01-1980
3864504	Szabo et al.	02-1975
4670281	Bradley	06-1987
5229160	Lang	7-1993
4726955	Horn et al	02-1988

Tonucci et al., Caretenoid Content of Thermally Processed Tomato-Based Food Products, Journal of Agriculture and Food Chemistry, Vol. 43, No. 3, pp. 579-86, 1995.

Dale et al., Concentration of Tomato Products, Analysis of Energy Saving Processes Alternatives, Journal of Food Science, Vol. 47, pp. 1853-58, 1982.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-14, 23-28, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Appellants added the claim phrase "comprises from 500-3,000 ppm of said chromoplast particles encapsulating crystalline lycopene." No specificational basis for this language was found.

Appellants' basis for this phrase is the concentration of lycopene rather than the "coloring material." Appellants argue that "the lycopene of the present invention is encapsulated within the chromoplast and this is clear for Applicant's specification as a whole" Again, applicants have provided no specific basis for this argument. The specification discloses that the coloring material contains partially broken chromoplasts and therefore it is reasonable that the instant coloring material contains lycopene in intact chromoplasts; lycopene in partially broken chromoplasts, and; lycopene free from broken chromoplasts. How much is in each form is not disclosed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 23-28 and 41-45 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. Applicants state that processing steps are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Appellants' specification states "conventional methods of extraction destroy the crystalline structure of this pigment" and that a "key aspect of the present invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast." (Emphasis added). A review of the specification discloses that

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the processing of tomatoes (except for the centrifugation) is "not essentially different [than] those conventionally carried out in the tomato processing industry." It is therefore unclear, at present, what process conditions (extraction steps) are being relied on to keep the chromoplast particles intact or partially intact.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because the scope of the phrase "high lycopene content tomato" is unknown. A term or phrase that at first appears indefinite, due to it being relative term, may be found adequately defined after a review of the specification. Applicants have not provided any basis in their specification for a solid definition of the phrase in question. The fact that certain courts and patent examiners have determined similar phrases to be definite may be due to the disclosure of the accompanying specifications.

Claims 1-14, 23-25, 28 and 45 to are rejected under 35 U.S.C. § 102(b)/102(e) as being anticipated by Graves *et al.* (U.S. Pat. No. 5,245,095)("Graves").

Graves teaches the production of a carotenoid extract. This involves fractionation of "any carotenoid natural source . . . such as . . . tomatoes" (col. 2, line 64 to col. 3, line 1). The fractionation is performed by first separating "the natural source into a carotenoid-containing

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liquid fraction and a pulp fraction", which can be performed by simply juicing the carotenoid source and filtering the juice through a course-mesh filter." (Col. 3, lines 8 to 16). Fractionation then occurs through precipitation of the carotenoid material and then separation of the precipitate can be "achieved by any conventional method, including centrifugation/decantation/freeze drying", etc., (Col. 4, lines 51 to 56). Further processing can be performed to further refine concentrated carotenoid, such as chemical hydrolysis "whereby the noncarotenoid constituents are rendered separable from the carotenoid(s) in an aqueous media." (Col. 2, lines 18 to 30).

The product can then be used as a pigment. (Col. 4, lines 57 to 60). The patent teaches that "[c]arotenoids, . . ., are valuable pigments useful for coloring various comestibles, such as margarine" (col. 1, lines 31 to 36). In the previous paragraph, the patentees mention that lycopene is the common carotenoid responsible for the color in tomatoes.

The product described and produced by the patented method of Graves is inherently the same as that now claimed. The Office does not have the facilities for examining and comparing appellants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed products. In the absence of evidence to the contrary, the burden is upon the applicants to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 1977); *Ex parte Gray*, 10 U.S.P.Q.2d 1922, 1923 (BPAI).

Graves is being applied as a 102(b) reference on those claims that recite centrifugation because the priority applications contain no disclosure of centrifugation. Otherwise, it is applied as a 102(e) reference.

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Claims 14 and 41-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tonucci *et al.* (Jnl. of Agricultural and Food Chemistry)("Tonucci").

Tonucci teaches that which is inherent in tomato-based products. Specifically, the data presented by Tonucci, found in Table 3, show that tomato paste has a lycopene content of around 550 ppm. This is higher than the amount claimed for the coloring material. The paste sample was obtained from "name-brand and store-brand tomato-based thermally processed foods" (page 580, col. 1). The article cites several authors who have discovered the antioxidant properties of lycopene (see Introduction). Further, Di Maresco *et al.*, is cited as discovering, in 1990, that "lycopene is the most efficient quencher of singlet oxygen which makes its presence in the diet of considerable interest".

Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brumlick *et al.* (U.S. Pat. No. 4,181,743)("Brumlick").

Brumlick discloses food flavorings and methods for their production. Example III discloses "pressed tomato juice containing the red coloring matter is boiled down or freeze dried." The products are "used for flavoring a variety of foods or as a low sodium salt substitute which may be spread by hand or from a container across food about to be eaten or mixed with foods to enhance their taste." (Col. 1, lines 45 to 49). While the patent discusses the products in connection with flavoring foods, the product of Example III inherently will add color, as contemplated by applicants, to the target food. It is also considered inherent, without a showing

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to the contrary, that the product of Example III has chromoplasts that contain crystalline lycopene.

Claims 1-3, 5, 6, 13 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szabo et al. (U.S. Pat. No. 3,864,504)("Szabo").

Szabo teaches a process to produce high concentration tomato puree by transforming colloids whereby tomatoes are triturated (i.e., comminuted) "in order to remove skin and seed parts, and partly to get a liquid consistence [and] easier to handle " The serum is then separated and the "red colored fraction of colloids is very little hygroscopic. With relatively little energy a 20-30 percent water content can be obtained {by} . . . centrifuge" and this fraction is can then be added back to the previously separated serum (a tomato product).

Again, it is also considered inherent, without a showing to the contrary, that the product of the cited patent has chromoplasts that contain crystalline lycopene.

Claims 1-5 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bradley (U.S. Pat. No. 4,670,281).

Bradley teaches the processing of tomatoes whereby tomatoes are macerated and subjected to a relatively mild (with respect to the prior art) centrifugal step to remove the liquid content and then the skins and seeds are removed. The final product of this process can be used in various products. (See patent disclosure).

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Claims 1-5, 7, 13 and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lang (U.S. Pat. No. 5,229,160).

Lang teaches a process for producing three tomato fractions produced by macerating the tomatoes and essentially washing with water the macerated tomatoes in a counter-current extractor. The "liquid portion or serum contains a large proportion of the aroma and flavor components of the tomatoes." The solids phase, after the skins and seeds have been removed and it has been dewatered "contains a high proportion of the viscosity inducing ingredients of the tomato and most of its color." (See generally col. 3, lines 17 to 57). "These fraction may be recombined in any combination allowing total flexibility when formulating pastes, juices or sauces." "The quality and stability of the color of the tomato products from the present process is significantly better that achieved by tradition procedures." (See col. 3, lines 59 to 68).

Claims 26 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Graves in view of Horn et al. (U.S. Pat. No. 4,726,955)("Horn").

Graves teaches that cited above but do not disclose the further size reduction of the concentrated carotenoids.

Horn teaches the prior use of a colloid mill to reduce the size of carotenoids to increase their solubility. (Col. 1, lines 31 to 45). It would have been obvious to those of ordinary skill in the art to use the colloid mill of the prior art, as taught by Horn, in the process of Graves for it intended and well taught use.

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Claims 1-14, 24-28, and 45 are rejected under 35 U.S.C. § 103 as being unpatentable Tonucci in view of Dale et al. (Jnl. Of Food Sci)("Dale").

Tonucci teaches that cited above. Specifically, they teach the importance of using lycopene as an antioxidant. They do not teach a coloring product that has 1000 ppm of lycopene but it would be obvious to one of ordinary skill in the art to make and to use a product that has as much lycopene as possible so as to maximize the antioxidant effects. Further, it would be obvious to one of ordinary skill in the art to use a lycopene product in conjunction with foods.

The claimed process steps in producing a tomato product, such as tomato paste, are all conventional and well known in the art, as evidenced by the other cited prior art. It is well known to clean tomatoes to remove mud and debris before they are processed. It is known to remove the seeds and to centrifuge the serum. This much is taught by Dale. It would be obvious to use lycopene-containing products such as tomato paste in conjunction with foods for the antioxidant effect of the lycopene. An application, e.g. coloring, of an old process is not patentable.

Claims 1-5, 7, 13 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Lang in view of Brumlick.

Lang teaches that which is cited above but does not mention (1)the cleaning of the tomatoes before macerating or (2)the freezing or dehydrating the final product of the process.

It is considered that the cleaning, freezing and dehydrating of tomatoes are such standard and commonly practiced process steps in the tomato processing industry that it would be obvious to one of ordinary skill in the art.

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Nevertheless, Brumlick teaches that cited above, i.e., freeze drying of the final tomato product.

It would have been obvious to one of ordinary skill in the art to freeze dry the tomato product of Lang as done by Brumlick because freeze drying has the well known benefits of reducing the weight and increasing shelf life of food products.

It would have been obvious to one of ordinary skill in the art to preclean the tomatoes of Lang since consumers demand clean, pure and safe food products.

(11) Response to Argument

The Declaration

For the record, the material that was submitted after the final rejection was not a declaration but merely documents meant to support the assertion found in a previous declaration. These documents have been reviewed and all comments concerning the previously submitted declaration are made with regard to the newly submitted documents.

First Paragraph of §112, Description

Appellants argue that the instant specification provides a clear basis for the added claim phrase "comprises from 500-3,000 ppm of said chromoplast particles encapsulating crystalline lycopene." The portion of the specification that purportedly provides basis for this phrase refers to lycopene rather than chromoplast particles. If appellants had show that 1ppm of chromoplast particles contained 1 ppm of lycopene crystals then an inherent basis would have been established. Appellants have not. The instant specification provides evidence for why they

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probably have not. On page 7, lines 2-3, appellants discloses that "chromoplasts present in lycopene-rich fruit, such as tomato, contain lycopene in crystalline form, and in vary concentration and crystal sizes." This indicates that the concentration of lycopene can vary from some unknown disclosed amount and therefore, one cannot assume that 1 ppm of chromoplast particles will contain 1 ppm of lycopene.

First Paragraph of §112, Enablement

The instant invention is not enabled as the application's disclosure fails to provide those of skill in the art the requisite information needed to process fruits, such as tomatoes, so as to preserve the integrity of the chromoplast particles. Appellants respond by stating that no "rigorous extraction" can be utilized. The only method by which they disclose that the particles can be separated is by centrifugation and that this is a gentle separation process. (Brief, page 15). There is no disclosure of the type of centrifuge that is used, or the parameters by which it is used. Appellants do not disclose any specific parameters by which to operate a centrifuge so that it will be gentle enough not to damage the chromoplast particles.

A review of the examples show that the color concentrate, after exiting the centrifuge, is further subjected to size reduction, in a colloid mill or a microcutter to yield the lycopene. No processing parameters are provided. Nothing in the examples mentions chloroplasts.

In the Hartal Declaration, it is stated that "gentle over-all treatment and breaking of the tomato into its competent parts is essential...." If this is essential, then appellants need to fully disclose what they mean by gentle treatment so that the invention can be practiced. It is not enough to disclose that the products are obtained or that the objective is to minimize

fractionation, but also how they are obtained so that those of skill in the art can reproduce those products. Appellants need to supply processing temperatures, pressures, times, equipment and its operation, etc.

It is noted that later in appellants' Brief, they cite to the Bradley patent, where is discusses the use of a centrifuge at high speed as degrading. (See brief, page 31). Clearly, as argued by appellants, the use of centrifuge is not always "gentle."

Second Paragraph of §112, Indefiniteness

Appellants assert that the scope of the phrase "high lycopene content tomato variety" is known. First, they rely on the Hartal Declaration for providing the scope. One cannot introduce new information into the record unless it relies on a disclosure predating the application date. If appellants were to insert such language into the specification or claims it would raise a new matter issue.

Appellants then cite to a 1923 Supreme Court case to justify the use of the claim phrase. It is interesting to note that the Board of Patent Appeals and Interferences has found the phrase to be repugnant to statute. It has stated that "high frequency" renders claims ambiguous inasmuch as specification neither sets forth a range nor defines the limits, scope, and meaning of relative term "high." *Ex parte Powell*, 155 USPQ 104 (BPAI 1967). This is considered to properly define the current requisite analysis for determining if a phrase is definite.

Claim 5 is therefore, interpreted broadly and this is reflected in the anticipatory rejections set forth above and below. No scope has been accurately ascertained and therefore, no value has been assigned to the phrase.

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102 Anticipation

Appellants interpret Graves as teaching the disruption of the tomato cell, i.e., the chromoplast membranes. Rather than assuming that Graves is referring to the chromoplast membrane instead of just the cells of the tomato, it is more informative to look at the process used by Graves. As set forth above, Graves uses the same type of processes as that disclosed by appellants. Appellants do not try to distinguish the claimed process from that of Graves to show that the product of Graves is not inherently the same as appellants.

Appellants do examine the process of Graves so far as to assume that the liquid fraction of Graves is different than the disclosed (but not claimed) liquid fraction of appellants. But they are, in fact, the same. Graves teaches screening the crushed tomatoes to separate out the solids, just as appellants do in step c. Graves performs a centrifugation, which inherently (because that is the operation of a centrifuge) removes solid material, just as appellants do. It is not clear in what way appellants believe that Graves is distinguishable with respect to appellants claimed process.

Appellants refer to the Hartal Declaration. But this declaration provides no data as to what amount chloroplast particles are found in the Graves' final product. It merely provides the opinion of Hartal and therefore, is not found persuasive. The burden is on appellants to show, through solid evidence, that the prior art process does not inherently produce the same results as appellants. The prior art process is the same, and therefore, the products are the same. If there is some critical step omitted by Graves, then it should be disclosed and claimed.

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With regard to Tonucci, appellants state that claims 14 and 43 require that the product be produced as recited in claim 1. Product-by-process claims are not limited to the process limitations. The product of Tonucci is inherently the same as claimed. Appellants state that the product of Tonucci has a Brix value of 30. This is of no consequence, as Claim 14 is not limited to any Brix value. The coloring material of claim 1 has a specific Brix value, but the product of claim 14 does not.

With regard to Brumlick, again, as done in traversing the rejection based on Graves, appellants attempt to distinguish the claims from the art by focusing on the "liquid fraction." In response, see comments above concerning focusing on the process as a whole with respect to the claims rather than characterizing the prior art narrowly.

Appellants then state the heat of Brumlick would destroy the chromoplasts. No evidence is supplied that this is the case. Rather, appellants, in their own specification, have stated how resilient the chromoplasts are to heat. Appellants also dry the chromoplasts. If a certain heat value is critical to the invention, it should be disclosed and claimed.

In reviewing the documents recently supplied to show the negative affects of heat when processing tomato products, it is noted that the times and temperatures tested were mostly outside of those used by Brumlick and those that are similar on show a slight decrease in lycopene concentration. These disclosures do not indicate that, as appellant states, the heat of Brumlick "would inevitably destroy any chromoplasts present."

With regard to the rejection based on Szabo, appellants again refer to the effects of heat and the treatment of the "liquid fraction." Specifically, they state "presumably, evaporation involves substantial heat." (Emphasis theirs). But appellants themselves dehydrate,

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presumably through evaporation that would involve high heat, and therefore it would appear that appellants are asserting both sides of the issue.

Appellants make mention that in "the present invention, the tomato smell and taste are largely eliminated (because the chromoplasts are maintained as claimed)." (Brief, page 30, emphasis theirs). But appellants do not claim this attribute. Further, there is no disclosure that the tomato smell and taste only arises if chromoplasts are broken.

With regard to the rejection based on Bradley, appellants assert that the temperatures used in the patent "will destroy chromoplasts." Again, no basis for this assertion is provided.

Again, it is noted that appellants themselves are stated how resilient chromoplasts are to heat.

Again, if the temperature is critical to the practice of the instant invention, then appellants should disclose what times and temperatures are critical.

Appellants also refer to Bradley's use of a centrifuge. As previously noted, appellants have placed no limitations on the use of their centrifuging step. Nothing is disclosed or claimed, that would indicate that there are limits on the operation of their centrifuge. If there are indeed limits, they should be disclosed and claimed.

With regard to the rejection based on Lang, appellants again refer to the heating. It s noted that the reference supplied by appellants, i.e., The White Book, Figure 1, on page 16 shows that if one were to apply boiling temperatures for 2 hours there is only a 24% decrease in lycopene. While not conclusive, it would appear that the prior art heating regimes are not as detrimental as appellants assert.

103, Obviousness

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With regard to the rejection of Graves in view of Horn, appellants state that Horn does not supply the asserted missing limitations. Because Graves indeed teaches the limitations that are asserted, Horn is not needed for those limitations. The same can be said of the obviousness rejection of Lang in view of Brumlick, Tonucci in view of Dale.

For the above reasons, it is believed that the rejections should be sustained.

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Primary Examiner Art Unit 1761

February 8, 2005

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